



DEPARTMENT OF HEALTH & HUMAN SERVICE

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New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

MAY 16 2001

WARNING LETTER

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Mr. Adam Licht, President
Scandia Seafood
260A Secaucus Road
Secaucus, NJ 07094

Ref: NYK 2001-68

Dear Mr. Licht:

The Food and Drug Administration (FDA) has information which shows that your firm has violated the Federal Food, Drug and Cosmetic Act.

During an inspection of your firm on March 20, 2001 it was revealed that your firm distributed portions of two shipments of seafood without suitable clearance from FDA. It was determined that [REDACTED] cartons of Yabbies and [REDACTED] of Red Emperor (Snapper) from entry number DL8-0021430-6 and [REDACTED] cases of Salmon from entry number DL8-0021426-4 (both of which your firm offered for entry into the United States through the port of New York/New Jersey), were distributed without a release from FDA. The failure to hold a shipment intact pending receipt of a May Proceed or Release Notice from FDA is a violation of the Federal Food, Drug and Cosmetic Act. We are hereby requesting U.S. Customs to order redelivery of these two shipments (copies enclosed).

Furthermore, it was determined from an interview with Douglas M. Metzgar, Warehouse Manager and Assistant Purchasing Agent that it has been the firm's practice, since January 2000, to routinely distribute product without first obtaining a release from FDA.

Failure to promptly correct this violation and prevent future violations may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred in secured storage.

Failure to promptly correct this violation and prevent future violations may also result in additional regulatory action without further notice, such as seizure, injunction, or detention without physical examination, to ensure that the product is held intact until released by FDA.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of such violations.

Your response should be directed to Mr. James Nelson, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Sincerely yours,

A handwritten signature in black ink that reads "Robert L. Hart". The signature is written in a cursive style with a large, stylized "R" and "H".

**Robert L. Hart
Acting District Director
New York District Office**